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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/596,207 | 08/21/2007 | Jeffrey A. Schuster | ZGNX-112 | 3424 |
| 24353 7590 07/30/2009 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303 | | | | |
| EXAMINER CAMPBELL, VICTORIA P | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3763 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 07/30/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,207

Applicant(s)

SCHUSTER ET AL.

Examiner

VICTORIA P. CAMPBELL

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-33 is/are pending in the application.
- 4a) Of the above claim(s) 14-17, 20-27 and 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-12, 18, 19 and 28 is/are rejected.
- 7) ☒ Claim(s) 5 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I and Species B in the reply filed on June 2, 2009 is acknowledged. However, the examiner does not agree that claims 1-6, 9-24, and 28-30 are all drawn to the elected species as stated by applicant in the response to restriction. The examiner notes that the limitation of claim 14 (that pressing the delivery orifice to the delivery site triggers the device) is not disclosed in conjunction with Species B, only species A, and therefore dependent claim 14 and claims 15-17 which depend from it are drawn to a non-elected species. Further, the limitation of claim 20, which requires that the cap have a frangible joint, is neither discussed nor depicted in regards to Species B as elected, but with regard to non-elected species A and C, and therefore dependent claim 20 and further claims 21-24 which depend from claim 20 are drawn to a non-elected species. Further, the frangible joint limitation is also present in independent claim 29, which is therefore directed to a non-elected species as is dependent claim 30. Therefore, the examiner hereby further withdraws claims 14-17, 20-24, 29, and 30 from consideration.

This is the initial Office Action based on the 10/596207 application filed August 21, 2007. Claims 1-6, 9-13, 18, 19, and 28 as elected are currently pending and considered below.

Information Disclosure Statement

2. The information disclosure statement filed November 15, 2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the form is blank. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information intended to be contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are generally messy and difficult to read, particularly Figure 3. Applicant is advised to take particular care with the various forms of cross-hatching used in the figures, as it can be difficult to distinguish between parts. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the button of claim 10

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet **within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.** The form and legal phraseology often used in patent claims, such as "means" and "said," should be

avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

7. Claim 1 is objected to because of the following informalities: the claim does not end in a period --,--.

8. Claim 13 is objected to because of the following informalities: the claim reads "allowing the lever to pivoted" in line 2 of the claim, but should read --allowing the lever to be pivoted--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-6, 9-13, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The examiner is requesting applicant thoroughly review the above claims and ensure that all references to "first state", "safe state", "second state", "ready to deliver state", "first position", "second position", etc. are used in relation to the proper parts of the device and that only one naming convention of "first/safe state" and "second/ready to deliver state" is chosen in order to simplify and clarify the claims.

11. Claim 6 recites the limitation "the collar" in line 7 of the claim and "the lever" in line 9 of the claim. There is insufficient antecedent basis for these limitations in the claim. Additionally, the claim appears to reference moving the latch, however the "safe position" and the "first position" are one in the same. Further, the claim recites "an additional safety mechanism" in line 7 of the claim and it is unclear whether this is a THIRD safety mechanism, or meant to refer back to the additional safety mechanism introduced in line 3 of the claim. The examiner has interpreted the claim as best as possible in the rejection below, such that the second recitation of an additional safety mechanism refers back to the first recitation.

12. Claims 9 and 10 recite the limitation "the lever" in lines 3 and 2 of the claims, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-4, 6, 9-12, 18, 19, and 28 as best understood by the examiner are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,558,348 B2 to Parsons in view of USPN 5,514,097 to Knauer.

Regarding the above claims, Parsons discloses a needle free injector (10) comprising an injection orifice (60), a mechanism for changing the injector from a first state to a second state (42), wherein the device is an attachment to the injector (Fig. 5). Parsons also discloses that the mechanism comprises a latch (Fig. 5) wherein the device further comprises a pin (43) and a means for actuating the pin (user) to move the

latch from the first to second position, an additional safety mechanism (37) to prevent triggering being disengaged when the collar (81) moves under the action of the lever (36), wherein the additional safety mechanism is a block (37) engaged when the lever is in a first position and disengaged when the lever is in a second position. Parsons also discloses that movement of the lever (42) exposes a button (36). Parsons also discloses a lever (36) wherein rotating the lever places the injector in the ready to deliver state (moves 37), and that the base of the lever actuates the safety mechanism (37).

Parsons fails to explicitly teach or disclose a cap. However, Knauer discloses an injection device having a cap (302) which prevents use of the device while in place. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the cap of Knauer to the device of Parsons in order to prevent contamination of the injection orifice prior to use. Additionally, if the cap were placed in specific configurations, it could act as a mechanism to prevent use of the device (ie: covering latch 42 or preventing lever 36 from being depressed). These configurations require only simple changes in shape of the cap of Knauer and therefore would have been obvious to one having ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

17. Claims 5 and 13 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763